

PATENT

Attorney Docket No. 8707-2161
163B – Gestion Capteur
Customer No.: 34313
Confirmation No.: 7566

REMARKS

Claims 1-27 are pending in this application. Claims 1, 14 and 21 have been amended.

Applicant respectfully traverses the grounds for Examiner's rejections listed below.

1. Claim rejections under 35 U.S.C. § 112, first paragraph

Claims 1-27 are rejected as failing to comply with the written description requirement. Independent claims 1 and 14 recite "means for preventing switching to a DDD pacing mode when a condition indicative of a suspected loss of atrial detection is detected"; and independent claim 21 recites "means for analyzing said sequence to detect a condition indicative of a suspected loss of atrial detection in order to prevent inappropriate switching to a DDD pacing mode". The Examiner asserts that there is no support for the recitation of "to a" in the rejected claims and asserts that the specification discloses an opposite reading of "in which the detection and correction of the defects of atrial capture or atrial under-detection are employed to avoid an inappropriate switch out of operating in a conventional DDD operating mode".

A. Sentence Construction

The Examiner construes the above sentence to mean that the detection and correction of the defects are employed to avoid an inappropriate switch *out of* operating in a conventional DDD operating mode. However, the Applicant intended a construction in which the detection and correction of the defects are employed to avoid an inappropriate *switch out* of operating in a conventional DDD operating mode. The Examiner's construction indicates starting in DDD operating mode and avoiding an "inappropriate" switch from DDD operating mode. However, Applicant intended the sentence to indicate that the inappropriate *switch out* would be to change

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to DDD operating mode.

B. Contextual Support

The specification discloses, "The quality of the detection of spontaneous cardiac signals and the quality of the capture of a stimulated cardiac event are essential to the effectiveness of the various analysis and control algorithms that are integrated into the implanted devices. Parameters are available for this purpose to allow the doctor to adjust the sensitivity of detection of spontaneous activity and the stimulation energy level necessary to stimulate a cardiac contraction (i.e., a capture) as best as possible." (See page 2, lines 3-13). The specification also discloses, "[I]t is an object of the invention to improve the auto-adjustment of the sensitivity and the stimulation energy values, suitable to avoid inopportune and useless misadjustments of these parameters. Broadly, the present invention concerns improved apparatus and signal processing methods that detect situations of atrial under-detection and loss of atrial capture, to be able to ensure the correct operation of the various algorithms operating the device. One aspect of the invention is directed to a device that is equipped with an automatic commutation operation, in which the detection and correction of the defects of atrial capture or under-detection are employed to avoid an inappropriate switch out of operating in a conventional DDD operating mode. This avoids unnecessarily stimulating the ventricle, and thus mitigates the possible noxious effects, from the hemodynamic point of view, of delivering such an inappropriate therapy." (See page 2, line 28 through page 3, line 7).

The specification incorporates by reference United States Patent No. 5,318,594 ("the '594 patent"). The '594 patent discloses, "It is another object of this invention to provide a cardiac

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pacemaker of the DDD type that will operate in the DDD mode solely during period of crisis, and will operate in the AAI mode outside of the period of crisis." ('594 Patent, Col. 1, line 67 through Col. 2, line 2).

The present invention ensures correct operation of the various algorithms operating the device through improved apparatus and signal processing methods that detect situations of atrial under-detection and loss of atrial capture, to be able to ensure the correct operation of the various algorithms operating the device. An automatic commutation operation, in which the detection and correction of the defects of atrial capture or under-detection are employed, avoids unnecessarily stimulating the ventricle and mitigates the possible noxious effects of delivering inappropriate therapy. Prior art signal processing methods may have mistakenly interpreted detection of situations of atrial under-detection and loss of atrial capture. The prior art signal processing methods may have interpreted these situations as a period of crisis and switched to operation in DDD mode. However, this invention discloses an active implantable medical device comprising a means for preventing switching to a DDD pacing mode when a condition indicative of a suspected loss of atrial detection is detected.

C. Priority Document Support

Applicant notes that this application claims priority from French Patent Application No. 02 10458, filed August 21, 2002, a certified copy of which was filed with the United States Patent and Trademark Office on September 11, 2003. Page 1, line 34 through page 2, line 3 of the French Patent Application recites, "la détection et la correction des défauts de capture ou de sous-détection auriculaires permet d'éviter un basculement inapproprié en mode DDD, évitant de

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stimuler le ventricule inutilement et palliant ainsi les possibles effets délétères, du point de vue hémodynamique, d'une telle situation inappropriée." Attached hereto as **Exhibit A** is a declaration from Laurent Bourdat stating that a more accurate translation of this passage is "the detection and correction of the defects of atrial capture or atrial under-detection are employed to avoid inappropriate switching to operating in a conventional DDD mode. This avoids unnecessarily stimulating the ventricle, and thus mitigates the possible noxious effects, from the hemodynamic point of view, of delivering such an inappropriate therapy."

M.P.E.P. § 201.16 relates to Right of Priority, Overcoming a Reference and states, "The foreign application may be considered in the same manner as if it had been filed in this country on the same date that it was filed in the foreign country, and the applicant is ordinarily entitled to any claims based on such foreign application that he or she would be entitled to under our laws and practice. The foreign application must be examined for the question of sufficiency of the disclosure under 35 U.S.C. 112, as well as to determine if there is a basis for the claims sought." The priority document provides sufficient written description for the subject matter of the claims.

Applicant has accordingly amended the specification to conform to the disclosure of the priority document as more accurately translated. Therefore, Applicant believes that the claims are supported by both the specification as filed and the priority document and respectfully asks the Examiner to reconsider and withdraw the § 112 rejection based on written description.

2. Claim rejections under 35 U.S.C. § 112, second paragraph

Pending claims 1-27 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Applicant has amended independent claims 1, 14 and 21 and believes that all claims

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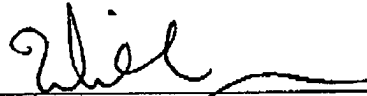
are now in allowable form and respectfully asks the Examiner to withdraw the § 112 rejection based on indefiniteness.

CONCLUSION

Reconsideration of this application in view of the foregoing remarks respectfully is requested. The Examiner is invited to call Applicant's undersigned attorney if doing so would expedite prosecution.

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Respectfully submitted,



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